

REMARKS

Amendment to the specification has been made on page 8 to overcome the Examiner's objection thereto by correcting an inadvertent error. In addition, the abstract has been amended to remove the term "means" therefrom in accordance with the Examiner's requirement.

Claims 10 and 11 have been amended to overcome the Examiner's rejection under 35 USC 112, second paragraph, and correct inadvertent errors therein. No new matter has been added.

Claims 1, 3, 10 and 11 have been rejected by the Examiner under 35 USC 102(b) as being anticipated by U.S. Patent 6,017,316 to Ritchart, et al. A factual determination of anticipation requires disclosure in a single reference of every element of the claimed invention and the Examiner must identify wherein each and every facet of the claimed invention is disclosed in the applied reference. Ex parte Levy 17 USPQ 2d 1461 (USPTO Board of Patent Appeals and Interferences 1990).

The Applicants submit that anticipation is established only when a single prior art referenced discloses, expressly or under principles of inherency, each and every element of the claimed invention. RCA Corp. v. Applied Digital Data Systems, Inc. 221 USPQ 385 (Fed. Cir. 1994).

Further, the Applicants submit that anticipation must meet strict standards, and unless all of the same elements are found in exactly the same situation and united in the

same way to form identical function in a single prior art reference, there is no anticipation. Tights, Inc. v. Acme-McCary Corp. et al. 191 USPQ 305 (CAFC 1976).

Bearing in mind this criteria, it is clear that the Ritchart, et al. reference does not anticipate claims 1, 3, 10 and 11.

First, it should be noted that Ritchart, et al. is directed to a system and method for automated biopsies wherein the present device functions for the aspiration and removal of severed tissue. With regard to claims 1 and 3, the method provides for evacuation of severed tissue from the needle by the vacuum and reducing vacuum and the needle before moving the blade from the second position to the first position.

This must be contrasted with the Ritchart, et al. reference, which the sample tissue is retained in the inner cutter 18 as it is withdrawn by friction and the inner walls of the cannula and by suction pressure within the lumen 20 caused by an open valve e. See column 7, lines 19-24.

In fact, Ritchart, et al. states that "the high vacuum pressure applied through the cutter lumen 20 from the proximal port 50 functions to retain the tissue specimen in the lumen during the ensuing transport of the cutter and specimen proximally to a suitable tissue receptacle (not shown) in a tissue chamber 58". (Emphasis Added)

Thus, the severed tissue is not evacuated through the needle. In fact, Ritchart, et al. teaches away from the present invention, in that the severed specimen exits through the distal port 26 into a medical waste receptacle or the like, thereby preventing blood and other waste from either clogging lumens 20 and 31 or apertures 56 or traversing proximately through the cutter lumen and discharging with the tissue specimen into the specimen receptacle. Column 7, lines 39-45.

Accordingly, the method taught by Ritchart, et al. does not include any teaching of evacuating severed tissue from the needle by vacuum. Since this step is not taught, there can be no anticipation under 35 USC 102(b).

Further, there is no inherent anticipation inasmuch as the device of Ritchart, et al. is meant to save tissue in a receptacle through the biopsy system and not discharge or remove severed tissue through a lumen. Accordingly, the Applicants respectfully request the Examiner to withdraw the rejection of claims 1 and 3 under 35 USC 102(b) on the basis of the Ritchart, et al. reference.

With reference to claims 10 and 11, in view of the fact that there is no vacuum source taught by Ritchart, et al., which is in communication with the needle lumen for causing tissue entry into the needle lumen through the port and for aspirating severed tissue through the lumen there is no anticipation. This structure is not taught or suggested by the Ritchart, et al. reference, as hereinabove noted, in the traverse of the rejection of claims 1 and 3 and thus the Applicants submit that a rejection of claims

10 and 11 is not sustainable under 35 USC 102(b) on the basis of the Ritchart, et al. reference. Withdrawal of this rejection is therefore respectfully requested.

Claims 2 and 7-9 have been rejected by the Examiner under 35 USC 103(a) as being unpatentable over U.S. 6,017,316 to Ritchart, et al. in view of U.S. 5,685,320 to Zimmon, et al.

In this rejection, the Examiner alleges that Ritchart, et al. discloses applying vacuum to the tissue to bring tissue into the port and moving the blade to sever the tissue, but fails to disclose regulating the vacuum applied to the tissue as well as not regulating the position of the blade to control the amount of tissue severed through blade movement. Thus, the Examiner reaches to Zimmon, et al. for a teaching that the size of a biopsy sample can be changed based upon the amount of vacuum or suction and the area that the opening receives the sample. The Examiner concludes it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Ritchart, et al. to include the steps of regulating the vacuum applied to the tissue and regulating the position of the blade to allow for more or less area to be opened to the tissue in order to modify the size of the biopsy sample as taught by Zimmon, et al.

While Zimmon, et al. teaches that the size of the biopsy sample is determined by a number of independently controllable factors, there is no teaching of a method which includes the evacuation of severed tissue through a

lumen. Inherently, Zimmon, et al. does not function in this manner in view of the fact that the object of the device is for retrieving samples for biopsy.

The present invention is directed to a method and apparatus for severing and evacuating tissue from a surgical site. This is accomplished through aspiration of the severed tissue through the needle. Accordingly, the vacuum and control method in accordance with the present invention is not compatible with either the Ritchart, et al. or Zimmon, et al. reference. As a result, the Applicants submit that the Examiner has not made a *prima facie* case of obviousness under 35 USC 103(a) on the basis of the Ritchart, et al. and Zimmon, et al. reference and respectfully request the withdrawal of rejection claims 2 and 7-9.

Claims 4 and 6 have been rejected by the Examiner under 35 USC 103(a) as being unpatentable over U.S. 6,017,318 to Ritchart, et al. in view of U.S. 6,120,462 to Hibner, et al. In a specific rejection of claims 4 and 6, the Examiner states that the amount of tissue severed is related to the movement of the blade as disclosed in Ritchart, et al.

However, Ritchart, et al. fails to disclose regulating the speed of movement of the blade and therefore the Examiner reaches to Hibner, et al. for a teaching of a biopsy device wherein the speed of the cutter is regulated. The Examiner then concludes it would have been obvious to one of ordinary skill in the art at the time the invention was made to regulate the speed of the blade as disclosed by

Ritchart, et al. in order to maintain the blade in an optimal range while translating through tissue.

Both the Ritchart, et al. and Hibner, et al. patents are directed to biting a piece of tissue for removal and depositing same in a receptacle. This was hereinabove discussed with regard to Ritchart, et al. and the same is true for Hibner, et al. As set forth in column 8, beginning at line 7, Hibner, et al. states, "the tissue extracted from the surgical patient is retrieved by the operator or by an assistant from tissue sampling surface 64." Thus, it does not flow through the lumen as provided in accordance with the present invention.

Thus, the Applicants submit that the Examiner has not made a *prima facie* case of obviousness in rejecting claims 4 and 6 under 35 USC 103(a) on the basis of the Ritchart and Hibner references. Withdrawal of this rejection is respectfully requested.

Claim 5 has been rejected by the Examiner under 35 USC 103(a) as being unpatentable over U.S. 6,017,316 to Ritchart, et al. in view of U.S. 5,685,322 to Zimmon, et al. in further in view of U.S. 6,120,462 to Hibner, et al.

The Applicants traverse this rejection on the basis that none of the references cited by the Examiner is hereinabove discussed include the severing of tissue and the aspiration of the same through a lumen and accordingly the coordination of a blade and vacuum as set forth in the claims of the present invention is not taught by any of the cited references nor is there any inherent teaching in view

of the significantly different operation of all of the devices set forth in the referenced patents.

In view of the arguments hereinabove set forth and amendment to the claims and specification, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectively requested.

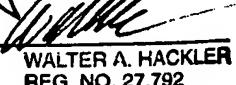
Respectfully submitted,



Walter A. Hackler, Reg. No. 27,792
Attorney of Record
2372 S.E. Bristol, Suite B
Newport Beach, California 92660
Tel: (949) 851-5010
Fax: (949) 752-1925

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS
BEING DEPOSITED WITH THE U.S. POSTAL SERVICE
AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED
TO: COMMISSIONER OF PATENTS AND TRADEMARKS,
WASHINGTON, D.C. 20231, ON

Aug 28 2003

8/14/03
(DATE SIGNED) 
WALTER A. HACKLER
REG. NO. 27,792